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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,306	03/11/2009	Song-Hua Ke	100788.0023US	5169
24392 7590 02/07/2011 FISH & ASSOCIATES, PC ROBERT D. FISH 2603 Main Street Suite 1000 Irvine, CA 92614-6232				
EXAMINER MYERS, CARLA J				
ART UNIT		PAPER NUMBER		
1634				
NOTIFICATION DATE		DELIVERY MODE		
02/07/2011		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rfish@fishiplaw.com  
patents@fishiplaw.com

# Office Action Summary

## Application No.

10/596,306

## Applicant(s)

KE ET AL.

## Examiner

Carla Myers

## Art Unit

1634

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-859)  
Paper No(s)/Mail Date \_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

## **DETAILED ACTION**

### **Sequence Compliance**

1. In claims 5, 6, 8 16 and 18, the assigned SEQ ID NOs have not been used to identify each sequence listed, as required under 37 CFR 1.821(d). As set forth in 37 CFR 1.821(d) "Where the description or claims of a patent application discuss a sequence that is set forth in the 'Sequence Listing' in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by 'SEQ ID NO:' in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application." For the response to this Office action to be considered complete, Applicants are required to amend the claims (and specification) to recite the appropriate sequence identifier in place of, e.g., "Ax," "Bx" etc.

### **Election/Restrictions**

2. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

the primers and nucleic acids of SEQ ID NO: "Ax," "Ay," "Bx," "By," "Cx" and "Cy"  
– i.e., SEQ ID NO: 1-72.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims

subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Claims 5 and 8-20 read on the species of SEQ ID NO: 1-48  
Claims 6 and 8-20 read on the species of SEQ ID NO: 49-72

The following claim(s) are generic: claims 1-4 and 7.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The recited primers and nucleic acids differ from one another with respect to their nucleotide structure such that each primer/nucleic acid consists of a different nucleotide sequence, and with respect to their specificity of hybridization, such that the primers/nucleic acids hybridize with a different specificity to particular HPV types (see Table 1A). The primers and nucleic acids thereby have a different chemical structure and different biological activity and effect. Thus, the claimed primers and nucleic acids do not have both a "common property or activity" and a common structure as would be required to show that the inventions are "of a similar nature."

Additionally, the technical feature of a combination of two forward primers and two reverse primers for amplifying HPV sequences was known in the art at the time the

invention was made. For example, Hirschhorn et al (PNAS. 2000. 97: 12164-12169; cited in the IDS) teach sets of primers for detecting sequence variation genotyping HPV sequences and methods of multiplex PCR to amplify nucleic acid sequences and detection of the amplified nucleic acid sequences using probes. Further, William et al (WO 02/103050; cited in the IDS) teaches type-specific primers and probes for detecting particular HPV genotypes. Accordingly, the technical feature linking the claimed invention of primers and probes for detecting HPV types was known in the art at the time the invention was made. Thereby, there is no special technical feature linking the claimed inventions.

In response to this Office action, Applicants are required to pick a specific combination of at least two forward primers selected from SEQ ID NO: 1-24, a combination of at least two reverse primers selected from SEQ ID NO: 25-48 (see claims 5 and 8) and a combination of at least two extension primers selected from SEQ ID NO: 49-72 (see claims 6 and 8). Applicants are also required to elect a nucleic acid to be examined with respect to claims 16-20. The elected nucleic acid must be commensurate with the elected primers. For example, if Applicants elect SEQ ID NO: 1, 2, 25, 26, 49 and 50, Applicants must elect one of these sequences to be examined with respect to claims 16-20. That is, Applicants may not elect, e.g., SEQ ID NO: 3 to be examined for claims 16-20 because such an election would not be commensurate with the elected combination of sequences.

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be

traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is 571-272-0747. The examiner can normally be reached on Monday-Thursday (6:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carla Myers/

Primary Examiner, Art Unit 1634